

Drug Manufacturer	Court Where Case Was Filed	Order / Opinion Last Issued	Contract Pharmacy Conditions at Issue	Court's Holding	Case Status
AstraZeneca	District of Delaware		<p>If a covered entity has an in-house pharmacy, it must use that pharmacy.</p> <p>If a covered entity does not have an in-house pharmacy, it may use only one contract pharmacy.</p>	<p>In an opinion that consolidated the <i>AstraZeneca</i>, <i>Novo Nordisk</i>, and <i>Sanofi</i> cases, the Third Circuit held that the 340B statute does not compel drug manufacturers to deliver covered drugs to an unlimited number of contract pharmacies. AstraZeneca's, Novo Nordisk's, and Sanofi's respective restrictions on delivery to contract pharmacies did not violate the statute. The court enjoined HHS from enforcing an interpretation of the statute that requires delivery of 340B drugs to an unlimited number of contract pharmacies.</p> <p>Sanofi also claimed that an alternative dispute resolution (ADR) rule that HRSA adopted in 2020 violated the Administrative Procedure Act's (APA) notice and comment requirements. The Third Circuit rejected that argument and held that HRSA lawfully promulgated the ADR rule.</p>	No further appeal pending.
Novo Nordisk	District of New Jersey	<p>January 30, 2023 (Opinion by the Third Circuit Court of Appeals)</p>	<p>If a covered entity has an in-house pharmacy, it must use that pharmacy.</p> <p>If a covered entity does not have an in-house pharmacy, it may use only one contract pharmacy.</p> <p>A covered entity without an in-house pharmacy may use multiple contract pharmacies in Novo Nordisk's discretion.</p>		

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Sanofi			<p>If a covered entity has an in-house pharmacy, it must use that pharmacy.</p> <p>If a covered entity does not have an in-house pharmacy, it may use only one contract pharmacy.</p> <p>If a covered entity without an in-house pharmacy agrees to provide claims data, it may use an unlimited number of contract pharmacies.</p>		
Novartis	District for the District of Columbia	May 21 (Opinion by the DC Circuit Court of Appeals)	<p>If a covered entity has an in-house pharmacy, it must use that pharmacy.</p> <p>If a covered entity does not have an in-house pharmacy, it may use only one contract pharmacy.</p>	<p>In an opinion that consolidated the <i>Novartis</i> and <i>United Therapeutics</i> cases, the DC Circuit held that the 340B statute does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities. Novartis's and United Therapeutics' respective contract pharmacy conditions did not violate the 340B statute on its</p>	<p>No further appeal pending.</p>

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United Therapeutics			<p>A covered entity may use only a contract pharmacy that it used during the first three quarters of the calendar year in 2020.</p> <p>If a covered entity did not have a contract pharmacy or in-house pharmacy during the first three quarters of the 2020 calendar year, the covered entity (1) may use only one contract pharmacy and (2) must regularly report claims data associated with all 340B contract pharmacy orders to a third-party platform.</p>	<p>face. The district court correctly set aside HRSA's enforcement letters against the manufacturers as arbitrary and capricious under the APA.</p>	

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Eli Lilly	Southern District of Indiana	October 29, 2021 (Order)	<p>If a covered entity has an in-house pharmacy, it must use that pharmacy.</p> <p>If a covered entity does not have an in-house pharmacy, it may use only one contract pharmacy.</p> <p>A covered entity also may use a contract pharmacy that is wholly owned by the covered entity.</p>	<p>The district court held that the HHS General Counsel's 2020 advisory opinion was arbitrary and capricious because it rested on a legally flawed assumption that the 340B statute unambiguously requires manufacturers to deliver covered drugs to an unlimited number of contract pharmacies. Additionally, HRSA's enforcement letter to Eli Lilly was arbitrary and capricious, given the agency's fluctuating positions regarding its ability to take enforcement actions relating to manufacturers' dealings with covered entities through contract pharmacy arrangements. The court set aside both the 2020 advisory opinion and enforcement letter as in violation of the APA and remanded the enforcement letter to HRSA for further consideration.</p>	Pending appeal before the Seventh Circuit, which heard oral arguments on October 31, 2022.